



## United States Department of Agriculture Animal and Plant Health Inspection Service 4700 River Road Riverdale, MD 20737

# Permit to Receive Soil Regulated by 7 CFR 330

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PERMITTEE NAME:Mr. Francisco Javier De FrutosPERMIT NUMBER:P330-18-00112COMPANY:Biome MakersAPPLICATION NUMBER:P525-180405-002RECEIVING ADDRESS:890 Embarcadero DriveDATE ISSUED:04/17/2018

Colaborators suite

West Sacramento, CA 95605

MAILING ADDRESS: 890 Embarcadero Drive

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West Sacramento, CA 95605

**PHONE:** (916) 661-3253

FAX: EXPIRES: 04/17/2021

PORTS OF ARRIVAL/PLANT INSPECTION STATIONS: AK, Anchorage; AL, Huntsville; AL, Mobile; AZ, Douglas; AZ, Lukeville; AZ, Naco; AZ, Nogales; AZ, Phoenix; AZ, San Luis; AZ, Tucson; CA, Calexico; CA, El Segundo; CA, Fresno; CA, Long Beach; CA, Oakland; CA, Ontario; CA, Otay Mesa; CA, Port Hueneme; CA, Sacramento; CA, San Diego; CA, San Francisco; CA, San Jose; CA, San Ysidro; CA, Tecate; CO, Denver; CT, Hartford; CT, New Haven; DE, Dover; DE, Wilmington; FL, Ft. Lauderdale; FL, Ft. Myers; FL, Ft. Pierce; FL, Jacksonville; FL, Key West; FL, Miami; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc.); FL, Orlando; FL, Pensacola; FL, Port Canaveral; FL, Port Everglades; FL, Sanford; FL, Tampa; FL, West Palm Beach; GA, Atlanta (Air Cargo Only - No Maritime shipments authorized); GA, Savannah; GU, Agana; HI, Hilo; HI, Honolulu; HI, Kahului; HI, Kailua-Kona; HI, Lihue; ID, Eastport; IL, Chicago; IN, Indianapolis; KY, Louisville; MA, South Boston; MD, Baltimore; MD, Beltsville; ME, Bangor; ME, Calais; ME, Houlton; ME, Portland; MI, Detroit; MI, Port Huron; MI, Romulus; MI, Sault Saint Marie; MN, Duluth; MN, Grand Portage; MN, International Falls; MN, Minneapolis; MO, Kansas City: MO. St. Louis: MP. Commonwealth of the Northern Mariana Islands: MS. Gulfport: MS. Port Bienville: MT, Raymond; MT, Roosville; MT, Sweetgrass; NC, Raleigh; NC, Wilmington; ND, Dunseith; ND, Pembina; ND, Portal; NJ, Linden; NM, Albuquerque; NM, Columbus; NM, SantaTeresa; NV, Las Vegas; NY, Albany; NY, Alexandria Bay; NY, Brooklyn; NY, Buffalo; NY, Champlain, Rouses Point; NY, Jamaica; NY, Newburgh; OH, Ashtabula; OH, Cincinnati; OH, Cleveland; OH, Columbus; OH, Toledo; OH, Wilmington; OK, Oklahoma City; OR, Portland: PA, Allentown; PA, Harrisburg; PA, Philadelphia; PA, Pittsburgh; PA, Scranton; PR, Aguadilla; PR, Carolina; PR, Fajardo; PR, Mayaguez; PR, Ponce; RI, Warwick/Providence; SC, Charleston; TN, Memphis; TN Nashville; TX, Austin; TX, Brownsville; TX, Corpus Christi; TX, Dallas; TX, Del Rio; TX, Eagle Pass; TX, El Paso; TX, Falcon; TX, Fort Hancock; TX, Galveston; TX, Hidalgo; TX, Humble; TX, Laredo; TX, Los Indios; TX, Pharr; TX, Port Arthur; TX, Presidio; TX, Progresso; TX, Rio Grande City; TX, Roma; TX, San Antonio; TX, Victoria; UT, Salt Lake City; VA, Dulles; VA, Norfolk; VI, St, Croix; VI, St, Thomas; VT, Berlin; WA, Blaine; WA, Oroville; WA, Port Angeles; WA, SeaTac; WA, Sumas; WI, Green Bay; WI, Milwaukee HAND CARRY:

Under the conditions specified, this permit authorizes the following:

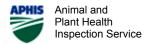
### **Quantity of Soil per Shipment and Treatment**

3 lbs or less: Sterilization will interfere with intended use - Your facility MUST be inspected and approved to receive this soil

#### PERMIT CONDITIONS

Permit Number P330-18-00112

THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.	DATE
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This permit authorizes the importation of soil from all foreign sources (except countries with sanctions or embargoes by U.S. State Department), for chemical/physical analysis including the isolation and/or culture of Deoxyribonucleic Acid (DNA) or Ribonucleic Acid (RNA) in a controlled laboratory environment at the named facility on the permit.

1.

- This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.
- If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

## 2. The permit holder must:

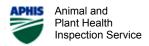
o maintain a valid PPQ 330 permit so long as any portion of the regulated soil remains untreated,

o not assign or transfer this permit to other persons without prior APHIS PPQ authorization, o maintain an official permanent work assignment, residence, or affiliation at the address on this permit,

o notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,

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o notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated soil.

o adequately mitigate environmental impacts resulting from unauthorized release of the regulated soil,

o notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,

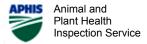
o devitalize/sterilize all regulated soil prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

- 3. All solid wood packing material (SWPM) accompanying the shipment must be in compliance with ISPM 15 treatment regulations and IPPC stamp requirements and enforcement. Noncompliant shipments will be treated, re-exported or destroyed at the consignee's expense.
- 4. All operations must be consistent with information submitted in association with the above listed APHIS-PPQ inspected facility and subject to the conditions below.
- 5. Soil must be shipped in a securely closed, watertight container (primary container, test tube, vial, etc.) which must be enclosed in a second, durable watertight container (secondary container).
- 6. The shipment must be free from foreign matter or debris, plants and plant parts including noxious weeds and infestations by other macroorganisms such as insects, Cyst nematodes, mollusks and acari. Authorized material found to be commingled with unauthorized material will be subject to the same action (i.e. re-export, destruction) as unauthorized material.
- 7. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: https://www.selectagents.gov/resources/APHIS-CDC\_Form\_4\_Guidance\_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: Peronosclerospora philippinensis (Peronosclerospora sacchari), Conothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines), Ralstonia solanacearum, Rathayibacter toxicus, Sclerophthora rayssiae, Synchytrium endobioticum, and Xanthomonas oryzae.
- 8. The imported article can be released without treatment at the port of entry to the permittee's address listed on the permit or label or to an authorized user only if the final destination is an approved facility listed at https://web01.aphis.usda.gov/PPQ/AuthSoilLabs.nsf/web?openform.

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WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)





9. The soil must not be used in field research or released into the environment before sterilization.

The soil must not be used for isolation or culture of organisms, or for extracting and concentrating organisms from the soil.

The soil must not be used as a growing medium.

- 10. For soil samples that originate in Hawaii and Puerto Rico, a copy of this permit and the samples must be presented to APHIS-PPQ for inspection and clearance prior to shipment. For soil samples that originate in the U.S. Virgin Islands, a copy of this permit and the samples must be presented to DHS-CBP for inspection and clearance prior to shipment. Following inspection, soil shipments from Hawaii, Puerto Rico, and the U.S. Virgin Islands are authorized to enter at any arrival point on the mainland U.S.
- 11. Further distribution (intrastate or interstate) of soil is not allowed without prior approval from Federal officials [State Plant Health Director or designee] (or from Federal officials with State concurrence): Access the website at http://www.aphis.usda.gov/ppq/sphd/ for a list of State Plant Health Offices. Access the website at

http://nationalplantboard.org/member/index.html for a list of State Plant Regulatory Officials.

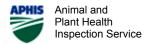
- 12. Further distribution of soil is not allowed without a permit from the receiving lab. While in storage, all soil must be kept locked (e.g. in freezer, cabinet) in the approved lab with access limited to authorized personnel or they will be in a restricted access building that requires a key card entry and access is restricted to authorized personnel only; or it must be in locked room restricted to authorized personnel only.
- 13. The soil must be handled as quarantined material until sterilized. This will include keeping the soil enclosed in containers when not in use and labeling all containers and/or storage areas:
- 14. All packing material, media, substrate, and shipping containers must be sterilized or destroyed as approved and prescribed by the permit conditions after removing the soil.
- 15. All unconsumed soil, containers and effluent must be autoclaved, incinerated or properly sterilized by the permittee at the conclusion of the project as approved and prescribed by the permit conditions.
- 16. Any water residues (effluent) from the processing of soil samples must be treated by an approved sterilization procedure such as hydroclave or autoclave.
- 17. All soil residues must be autoclaved.

**Autoclaving Waste** 

- a. Waste must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The

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autoclave tape or other indicator on each container must be checked to verify color change before disposal.

- c. The autoclave must be professionally calibrated annually and a written record must be maintained.
- d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores (e.g. Geobacillus species) that are rendered unviable at 121 degrees C. You must follow the manufacturery's instructions. If any growth is observed, you must have the autoclave serviced and retested.
- 18. Equipment and supplies used to conduct operations or that have contacted the soil must be decontaminated using one of the following methods:
- (a) Material can be soaked in a fresh bleach solution of 10 percent (1:10) for at least 30 minutes. (1:10 is a convention that means 1 in 10 or1 part 9 parts = 10 parts total, which is a 10 percent solution)
- (b) Material can be soaked in 70 percent ethanol
- (c) Flamed with ethanol
- (d) Treated with quaternary ammonium compounds. Note also that autoclaving, hydroclave, incineration, and dry heat sterilization are also acceptable sterilization/decontamination methods.
- 19. Upon issuance of this permit (i.e., a signed PPQ 330), you will need to request the PPQ Form 550 Black/White labels at least 5 days in advance of shipping date. If you applied online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to BlackWhiteGreenYellowlabelrequest@aphis.usda.gov. All email requests must come from the permit holder or appointee, if requested by the appointee the permit holder must be Ccýd on all requests. Specify the approved port as listed on the permit and the total number of labels needed in multiples of four. You may request additional labels the same way. We will send you the labels by email as a pdf.

However, the PPQ Form 550 Black/White label is not required on shipments of soil that originate in Hawaii, Puerto Rico, and the U.S. Virgin Islands

A label must be attached with clear tape to the exterior of each package being imported under this permit. The labels will include detailed shipping instructions. You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

All labels must be printed in color. Failure to do so may result in refused entry or destruction of your package.

Enclose the following supplemental information in each shipment:

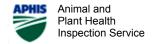
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- Permittee Name
- Permit number
- Label number

Underlying packaging/wrapping must carry the address, billing, and any other information required to direct the shipment to its final destination (i.e., the permit holder's address; N.B., USDA APHIS does not defray any additional shipping costs incurred for transiting the shipment through an inspection station as the initial US destination).

## **END OF PERMIT CONDITIONS**

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